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Attorneys for Plaintiffs
ALZA Corporation and
Janssen Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALZA CORPORATION and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT

In this patent infringement action, Plaintiffs ALZA Corporation ("ALZA") and Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs"), for their complaint against Defendant Sandoz Inc., allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the filing by Sandoz Inc. of Abbreviated New Drug Application ("ANDA") No. 205714 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of

CONCERTA® prior to the expiration of U.S. Patent No. 8,163,798 and U.S. Patent No. 8,629,179.

PARTIES

2. Plaintiff ALZA is a Delaware corporation, having its principal place of business at 700 Eubanks Drive, Vacaville, California 95688.

3. Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation, having a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. On information and belief, Defendant Sandoz Inc. is a company organized under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. On information and belief, Sandoz has a facility at One Health Plaza, Building 436, Room 4017A, East Hanover, New Jersey 07936. Sandoz is registered to do business in New Jersey under Business I.D. No. 0100097265.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. §§ 271(a), 271(b), 271(c), and 271(e)(2) specifically.

6. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. On information and belief, Sandoz Inc. formulates, manufactures, packages, markets, distributes, and sells generic pharmaceutical products. On information and belief, those products are marketed, distributed, and sold in the District of New Jersey and throughout the United States.

8. On information and belief, Sandoz Inc. is the owner of ANDA No. 205714.

9. On information and belief, Sandoz Inc. will market, distribute, and/or sell the generic products that are the subject of ANDA No. 205714 in the District of New Jersey.

10. This Court has personal jurisdiction over Sandoz Inc. because Sandoz Inc. maintains a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz Inc. has admitted that its principal place of business is in New Jersey in numerous actions, such as at least *Janssen Pharmaceuticals Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 13-06929 (CCC)(MF); *Cornerstone Therapeutics Inc. et al. v. Sandoz Inc.*, C.A. No. 13-05723 (NLH)(AMD); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 13-05815 (MLC)(DEA).

11. This Court also has personal jurisdiction over Sandoz Inc. by virtue of the fact that by filing ANDA No. 205714 for generic methylphenidate hydrochloride extended-release tablets, Sandoz Inc. has, *inter alia*, committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff ALZA in New Jersey. This Court has personal jurisdiction over Sandoz Inc. for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

12. Sandoz Inc. has submitted to the personal jurisdiction of the United States District Court for the District of New Jersey in numerous actions, such as at least *Janssen Pharmaceuticals Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 13-06929 (CCC)(MF); *Cornerstone Therapeutics Inc. et al. v. Sandoz Inc.*, C.A. No. 13-05723 (NLH)(AMD); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 13-05815 (MLC)(DEA); *Aptalis Pharma US Inc. et al. v. Sandoz Inc.*, C.A. No. 13-4290 (MLC)(LHG); *Shionogi & Co., Ltd v. Sandoz Inc.*, C.A. No. 12-cv-07907 (FLW)(LHG).

13. Personal jurisdiction over Sandoz Inc. is also proper because, on information and belief, Sandoz Inc. maintains continuous and systematic contacts with the State of New Jersey, including the maintaining a principal place of business in New Jersey, and the

sale and use of Sandoz Inc.'s products in New Jersey, so as to reasonably allow jurisdiction to be exercised over it. On information and belief, Sandoz Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey. For example, on information and belief, Sandoz Inc. holds a current "Manufacturer and Wholesale" pharmacy license from the State of New Jersey.

14. On information and belief, this Court has personal jurisdiction over Sandoz Inc. by virtue of, among other things: (1) its prior consent to be sued in New Jersey; (2) its systematic and continuous contacts with New Jersey, including having its principal place of business in New Jersey; and (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm to Plaintiffs in New Jersey.

15. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

GENERAL ALLEGATIONS

16. On April 24, 2012, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,163,798 ("the '798 Patent"). A true and correct certified copy of the '798 Patent is attached hereto as Exhibit A.

17. Plaintiffs own all rights, title and interest in the '798 Patent, including all rights needed to bring this action in Plaintiffs' names.

18. ALZA is the current assignee of the '798 Patent.

19. On January 14, 2014, the USPTO issued U.S. Patent No. 8,629,179 ("the '179 Patent"). A true and correct certified copy of the '179 Patent is attached hereto as Exhibit B.

20. Plaintiffs own all rights, title and interest in the '179 Patent, including all rights needed to bring this action in Plaintiffs' names.

21. ALZA is the current assignee of the '179 Patent.

22. ALZA manufactures the drug covered by the FDA approved New Drug Application ("NDA") No. 21-121 and marketed under the registered tradename CONCERTA®, the active ingredient of which is methylphenidate hydrochloride ("CONCERTA" or "the CONCERTA drug product"), in the United States.

23. Janssen Pharmaceuticals, Inc. holds NDA No. 21-121 for CONCERTA.

24. Marketing of CONCERTA is authorized in four dosage strengths (*i.e.*, 18 mg, 27 mg, 36 mg and 54 mg) by NDA No. 21-121.

25. CONCERTA is covered by one or more claims of the '798 Patent and/or the '179 Patent, which is listed in connection with CONCERTA in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" CONCERTA. *See* 21 U.S.C. § 355(b)(1).

26. On information and belief, Sandoz Inc. filed ANDA No. 205714 with the FDA seeking approval to market generic copies of the 54 mg dosage strength of the CONCERTA drug product (the "ANDA product") prior to the expiration of the '798 Patent and/or the '179 Patent. On information and belief, if ANDA No. 205714 is approved by the FDA, Sandoz Inc. will, prior to the expiration of the '798 Patent and/or the '179 Patent, begin making, selling, offering for sale, marketing, distributing, and/or importing generic copies of the 54 mg dosage strength of the CONCERTA drug product, and doctors and patients will use the ANDA product for the indications found in the approved generic label.

27. Pursuant to FDA regulation 21 C.F.R. § 314.94, Sandoz Inc.'s ANDA product must have the same dosage strength as CONCERTA and must be bioequivalent to CONCERTA.

28. On information and belief, Sandoz Inc. has asserted to the FDA that its ANDA product has a dosage strength of 54 mg and is bioequivalent to CONCERTA.

29. On information and belief, Sandoz Inc. has represented that the Reference Listed Drug ("RLD") of its ANDA No. 205714 is CONCERTA.

30. Sandoz Inc. has represented that it has included in ANDA No. 205714 a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '798 Patent and the '179 Patent are invalid.

31. On or about May 6, 2014, Plaintiffs received a letter dated May 5, 2014 (the "notice letter"), purporting to be notice of Sandoz Inc.'s ANDA No. 205714 and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). The Paragraph IV certification(s) alleged that the '798 Patent and '179 Patent were invalid. Sandoz Inc. did not provide any basis for asserting that the ANDA product does not infringe the '798 Patent or the '179 Patent in its notice letter.

32. Counsel for Plaintiffs and Sandoz Inc. were unable to agree to terms of access to Sandoz Inc.'s ANDA No. 205714 by Plaintiffs under 21 U.S.C. § 355(j)(5)(C)(i)(III). Sandoz Inc. refused to allow Plaintiffs access to Sandoz Inc.'s ANDA No. 205714 on the same terms this Court found reasonable in another case involving the same RLD and the same patents. *See Alza Corp. et al. v. Par Pharma., Inc. et al.*, C.A. No. 13-1104-RGA, D.I. 78 (D. Del. Dec. 17, 2013), D.I. 80 (Dec. 20, 2013).

33. This action is being commenced within forty-five days of the date of the notice letter.

34. On information and belief, Sandoz Inc. made the decision to and did file ANDA No. 205714 and "Paragraph IV" certification(s).

35. On information and belief, Sandoz Inc. was necessarily aware of the '798 Patent and the '179 Patent when it filed ANDA No. 205714 and submitted "Paragraph IV" certification(s) to the FDA in ANDA No. 205714.

36. On information and belief, Sandoz Inc. did not have an adequate good-faith basis for filing the "Paragraph IV" certification regarding the '798 Patent or the '179 Patent accompanying its ANDA.

37. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sandoz Inc.'s filing of ANDA No. 205714 seeking FDA approval to market generic copies of the 54 mg dosage strength of the CONCERTA drug product is an act of infringement of one or more claims of the '798 Patent and/or the '179 Patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of the FDA's approval for ANDA No. 205714 be a date which is not earlier than the expiration date of the '798 Patent and the '179 Patent, including any extensions of those dates.

COUNT I: INFRINGEMENT OF THE '798 PATENT

38. Plaintiffs incorporate and reallege paragraphs 1 through 37 above, as if set forth in full herein.

39. On information and belief, the commercial manufacture, use, offer for sale, marketing, distribution, and/or importation into the United States of the ANDA product is covered by the '798 Patent.

40. Sandoz Inc. had knowledge of the '798 Patent when it submitted and filed ANDA No. 205714.

41. Sandoz Inc. did not provide any basis for asserting that the ANDA product does not infringe the '798 Patent in its notice letter.

42. Sandoz Inc.'s filing of ANDA No. 205714 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, marketing, distributing,

and/or importation of the ANDA product before the expiration date of the '798 Patent is an act of infringement of the '798 Patent under 35 U.S.C. § 271(e)(2).

43. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA product will infringe one or more claims of the '798 Patent.

44. On information and belief, the use of the ANDA product in accordance with and as directed by the proposed labeling for the products will infringe one or more claims of the '798 Patent.

45. On information and belief, unless enjoined by this Court, Sandoz Inc. plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA product and its proposed labeling immediately following the FDA's approval of ANDA No. 205714.

46. On information and belief, Sandoz Inc. knew or was willfully blind to knowing that the ANDA product and its proposed labeling are especially made or adapted for use in infringing the '798 Patent, and that the ANDA product and its proposed labeling are not suitable for any substantial noninfringing use.

47. On information and belief, Sandoz Inc., including by making and distributing the ANDA product and its proposed labeling, intends to cause others to perform acts that Sandoz Inc. knows will infringe one or more claims of the '798 Patent.

48. On information and belief, unless enjoined by this Court, Sandoz Inc. plans and intends to, and will, actively induce infringement of the '798 Patent immediately following the FDA's approval of ANDA No. 205714.

49. On information and belief, unless enjoined by this Court, Sandoz Inc. plans and intends to, and will, contribute to the infringement of the '798 Patent immediately following the FDA's approval of ANDA No. 205714.

50. The foregoing actions by Sandoz Inc. constitute, and/or will constitute, direct infringement of the '798 Patent, active inducement of others to infringe the '798 Patent, and/or contribution to the infringement by others of the '798 Patent.

51. On information and belief, Sandoz Inc. acted without a reasonable basis for believing that it would not be liable for infringing the '798 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '798 Patent.

52. Unless Sandoz Inc. is enjoined from infringing the '798 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '798 Patent, Plaintiffs will suffer irreparable injury.

53. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Sandoz Inc.'s ANDA No. 205714 to be a date which is not any earlier than the expiration date of the '798 Patent, including any extensions of that date.

54. Plaintiffs do not have an adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '179 PATENT

55. Plaintiffs incorporate and reallege paragraphs 1 through 37 above, as if set forth in full herein.

56. On information and belief, the commercial manufacture, use, offer for sale, marketing, distribution, and/or importation into the United States of the ANDA product is covered by the '179 Patent.

57. Sandoz Inc. had knowledge of the '179 Patent when it submitted and filed ANDA No. 205714.

58. Sandoz Inc. did not provide any basis for asserting that the ANDA product does not infringe the '179 Patent in its notice letter.

59. On information and belief, Sandoz Inc.'s filing of ANDA No. 205714 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, marketing, distributing, and/or importation of the ANDA product before the expiration date of the '179 Patent is an act of infringement of the '179 Patent under 35 U.S.C. § 271(e)(2).

60. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA product will infringe one or more claims of the '179 Patent.

61. On information and belief, the use of the ANDA product in accordance with and as directed by the proposed labeling for the products will infringe one or more claims of the '179 Patent.

62. On information and belief, unless enjoined by this Court, Sandoz Inc. plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA product and its proposed labeling immediately following approval of ANDA No. 205714.

63. On information and belief, Sandoz Inc. knew or was willfully blind to knowing that the ANDA product and its proposed labeling are especially made or adapted for use in infringing the '179 Patent, and that the ANDA product and its proposed labeling are not suitable for any substantial noninfringing use.

64. On information and belief, Sandoz Inc., including by making and distributing the ANDA product and its proposed labeling, intends to cause others to perform acts that Sandoz Inc. knows will infringe one or more claims of the '179 Patent.

65. On information and belief, unless enjoined by this Court, Sandoz Inc. plans and intends to, and will, actively induce infringement of the '179 Patent immediately following the FDA's approval of ANDA No. 205714.

66. On information and belief, unless enjoined by this Court, Sandoz Inc. plans and intends to, and will, contribute to the infringement of the '179 Patent immediately following the FDA's approval of ANDA No. 205714.

67. The foregoing actions by Sandoz Inc. constitute, and/or will constitute, direct infringement of the '179 Patent, active inducement of others to infringe the '179 Patent, and/or contribution to the infringement by others of the '179 Patent.

68. On information and belief, Sandoz Inc. acted without a reasonable basis for believing that it would not be liable for infringing the '179 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '179 Patent.

69. Unless Sandoz Inc. is enjoined from infringing the '179 Patent, actively inducing infringement of the '179 Patent, and/or contributing to the infringement of the '179 Patent, Plaintiffs will suffer irreparable injury.

70. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Sandoz Inc.'s ANDA No. 205714 to be a date which is not any earlier than the expiration date of the '179 Patent, including any extensions of that date.

71. Plaintiffs do not have an adequate remedy at law.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment that the '798 Patent and the '179 Patent are valid and enforceable;

B. The entry of judgment that the '798 Patent and the '179 Patent would be directly infringed by the ANDA product, either literally or under the doctrine of equivalents; that Sandoz Inc.'s submission of ANDA No. 205714 is an act of infringement of the '798 Patent and

the '179 Patent; and that Sandoz Inc.'s making, using, offering to sell, selling, marketing, distributing, or importing the ANDA product, or any product that infringes the '798 Patent or the '179 Patent, prior to the dates that the '798 Patent and the '179 Patent expire, would infringe, actively induce infringement, and contribute to the infringement of the '798 Patent or the '179 Patent;

C. The entry of an order pursuant to 35 U.S.C. § 271(e)(4) directing the FDA to not approve Sandoz Inc.'s ANDA No. 205714, or any product or compound that infringes the '798 Patent or the '179 Patent, or, as the case may be, to change the effective date of approval of Sandoz Inc.'s ANDA No. 205714 to a date not earlier than the dates that the '798 Patent and the '179 Patent expire, including any extensions of those dates;

D. The entry of a permanent injunction, enjoining Sandoz Inc., its officers, directors, agents, servants, employees, successors and assigns, and all others in concert and privity with them, from making, using, offering to sell, selling, marketing, distributing, or importing the ANDA product, or any other products not colorably different, that infringe the '798 Patent or the '179 Patent, and from inducing or contributing to the infringement of the '798 Patent or the '179 Patent, until after the expiration of the '798 Patent or the '179 Patent, including any extensions of those dates;

E. Damages or other monetary relief, including prejudgment interest, if Sandoz Inc. engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of the ANDA product, or any other products that infringe the '798 Patent or the '179 Patent, or the inducement or contribution of the forgoing, prior to the expiration of '798 Patent or the '179 Patent, including any extensions of those dates;

F. The entry of judgment that, in view of Sandoz Inc.'s relevant acts, this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees for bringing and prosecuting this action;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. An award of Plaintiffs' costs and expenses in bringing and prosecuting this action; and

I. Such other and further relief as the Court may deem just and proper.

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s/ Sheila F. McShane

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